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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,237	11/10/2000	Philip Henry Coelho	30195-pa	3030

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1656

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/709,237

Applicant(s)

COELHO ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10-12, 14, 15 and 19-40 is/are pending in the application.
- 4a) Of the above claim(s) 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10, 11, 14, 15 and 19-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 July 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 10-12, 14, 15 and 19-40 are pending.

Applicants' amendment filed July 19, 2005 is acknowledged. Applicant's response has been fully considered. Claims 10, 19, 22-26 and 34-38 have been amended. Claim 12 is a non-elected invention, thus withdrawn from consideration. Therefore, claims 10-11, 14, 15 and 19-40 are examined.

### **Withdrawn Informalities**

2. The previous objection to the specification is withdrawn in view of applicant's amendment to the specification, and applicant's response at pages 10-11 in the amendment filed July 19, 2005.

### **Withdrawn Claim Rejections - 35 USC § 112**

4. The previous rejection of claims 22-26 and 34-38 under 35 U. S. C. 112, second paragraph, is withdrawn in view of applicant's amendment to the claim, and applicant's response at page 12 in the amendment filed July 19, 2005.

### ***Informalities***

The disclosure is objected to because of the following informalities:

5. Figs. 5-12 (marked-up copies) are objected to because the clean copies of drawings have not been submitted. Please submit the complete set of formal drawings.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to

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which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 10-11, 14, 15 and 19-40 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter Rejection.

Claims 10-11, 14, 15 and 19-40 are directed to a thrombin composition free of fibrin clots, consisting essentially of plasma, EtOH and  $\text{CaCl}_2$  (or a source of calcium ion). The specification indicates the procedure of invention is comprised of three steps, the first two of which should occur at the same time: (1). Preparing a fraction enriched in prothrombin by use of Ethanol to substantially enhance the concentration of prothrombin and at the same time remove or denature naturally occurring ingredients within plasma; (2). Adding calcium ions to the enriched prothrombin solution and briefly agitating the solution to convert the pro-thrombin to stable, long term thrombin; and (3). Expressing the thrombin solution through a filter to remove particulate matter (page 8). The specification also describes the preparation of thrombin in the apparatus of Fig. 1 using the same principles (pages 13-16). Thus, the specification only describes the preparation of thrombin from plasma by concentrating the prothrombin fraction using EtOH and converting prothrombin to thrombin with  $\text{CaCl}_2$ , where the plasma proteins and fibrin clots have been removed from plasma by filtration, the thrombin composition obtained after filtration no longer contains the intact plasma. From the description of the preparation of the thrombin composition in the apparatus of Fig. 1 (pages 13-16), it appears that before

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filtration the composition contains thrombin, fibrin clots, plasma, EtOH and CaCl<sub>2</sub>, and after filtration the composition is free of fibrin clots, but does not contain intact plasma (e.g., plasma proteins such as fibrinogen have been removed). The lack of description of a thrombin composition free of fibrin clots, consisting essentially of plasma, EtOH and CaCl<sub>2</sub> (or a source of calcium ion) in the original specification and the lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

*Response to Arguments*

Applicants indicate the claims are supported by the specification using the processing set of the invention (pages 13-15 of the specification), where no particulates (e.g., fibrin clots) from the plasma in the thrombin that is present in the thrombin dispensing syringe, thus the claims which refer to thrombin “free of fibrin clots” are supported by the specification (page 11 of the response).

Applicants’ response has been fully considered, however, the argument is not found persuasive because the prepared thrombin composition obtained either before filtration or after filtration cannot be free of fibrin clots and in the mean time consisting essentially of plasma, ethanol and CaCl<sub>2</sub>, since the plasma proteins are separated from plasma and fibrin clots formed when ethanol and CaCl<sub>2</sub> are added to the plasma. Thus, if the thrombin composition obtained after filtration, the composition is free of fibrin clots but no longer contains plasma. Therefore, the claims refer to a thrombin composition free of fibrin clots, consisting essentially of plasma, EtOH and CaCl<sub>2</sub> are not supported by the specification.

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***Conclusion***

7. No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Chih-Min Kam, Ph. D. *CMK*

Patent Examiner

CMK

September 22, 2005



**KATHLEEN M. KERR, PH.D.  
SUPERVISORY PATENT EXAMINER**